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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,478	06/27/2005	Jonathan M. Lee	PTQ-0065	2533

26259 7590 05/04/2006

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EXAMINER	
AEDER, SEAN E	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/516,478	LEE, JONATHAN M.	
	Examiner	Art Unit	
	Sean E. Aeder, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-30 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6, as specifically drawn to a method for diagnosing cancer comprising measuring EEF1A2 gene amplification.

Group II, claim(s) 1-6, as specifically drawn to a method for diagnosing cancer comprising measuring EEF1A2 mRNA levels.

Group III, claim(s) 1-6, as specifically drawn to a method for diagnosing cancer comprising measuring EEF1A2 protein levels.

Group IV, claim(s) 1-6, as specifically drawn to a method for diagnosing cancer comprising measuring EEF1A2 protein activity.

Group V, claim(s) 7, as specifically drawn to a kit for prognosticating and/or diagnosing cancer comprising means for measuring EEF1A2 gene amplification.

Group VI, claim(s) 7, as specifically drawn to a kit for prognosticating and/or diagnosing cancer comprising means for measuring EEF1A2 mRNA levels.

Group VII, claim(s) 7, as specifically drawn to a kit for prognosticating and/or diagnosing cancer comprising means for measuring EEF1A2 protein levels.

Group VIII, claim(s) 7, as specifically drawn to a kit for prognosticating and/or diagnosing cancer comprising means for measuring EEF1A2 protein activity.

Group IX, claim(s) 8-28, as specifically drawn to a method of inhibiting EEF1A2 expression in a tumor cell and a method of treating cancer comprising administering to a patient an inhibitor of EEFIA2 expression.

Group X, claim(s) 24 and 26-28, as specifically drawn to a method of treating cancer comprising administering to a patient an inhibitor of EEFIA2 activity.

Group XI, claim(s) 29-30, as specifically drawn to a screening assay comprising measuring an agent's ability to inhibit EEF1A2 expression.

Group XII, claim(s) 29-30, as specifically drawn to a screening assay comprising measuring an agent's ability to inhibit EEF1A2 activity.

The inventions listed as groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-XII appears to be that they all relate to the special technical feature of an EEF1A2 gene.

However, Lund et al (Genomics, 1996, 36:359-361) teaches an EEF1A2 gene.

Therefore, the technical feature linking the inventions of groups I-XII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Accordingly, groups I-XII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b),"

1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Species

Claims 1, 2, 4, 5, 8, 11, 12, 15, and 29 are generic to a plurality of disclosed patentably distinct species of **cancers and tumor cells corresponding to said cancers** comprising the following: ovarian cancer and ovarian cancer cells, breast cancer and breast cancer cells, colorectal cancer and colorectal cancer cells (see claims 2, 5, and 11). The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each species represent separate and distinct cell types with different morphologies and functions such that one species could not be interchanged with the other. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Claims 8-10, 15-23, and 25 are generic to a plurality of disclosed patentably distinct species of **antisense oligonucleotides** comprising the following: antisense oligonucleotides complementary in sequence to a regulatory region of a gene which encodes EEF1A2 (claim 19), antisense oligonucleotides complementary in sequence to a transcription initiation region of a gene which encodes EEF1A2 (claim 20), antisense oligonucleotides complementary in sequence to a region which precedes or spans the translation initiation codon of a gene which encodes EEF1A2 protein (claim 21), antisense oligonucleotides complementary in sequence to an untranslated region of a mRNA which encodes EEF1A2 (claim 22), and antisense oligonucleotides complementary in sequence to a 3' untranslated region of the mRNA (claim 23). The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species represent separate and distinct products which are made by materially different methods, and which have different modes of operation, different functions and different effects. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify

the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER